Supreme Court, U.S.
FILED
FEB 17 2016
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

DAVID ZUBIK, *et al.*,

Petitioners,

v.

SYLVIA MATTHEWS BURWELL, SECRETARY OF HEALTH AND HUMAN SERVICES, *et al.*,

Respondents.

ON WRITS OF CERTIORARI TO THE UNITED STATES COURTS OF APPEALS FOR THE THIRD, FIFTH, TENTH AND DC CIRCUITS

BRIEF OF *AMICI CURIAE* AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, PHYSICIANS FOR REPRODUCTIVE HEALTH, AMERICAN ACADEMY OF FAMILY PHYSICIANS, AMERICAN NURSES ASSOCIATION, *et al.* IN SUPPORT OF THE GOVERNMENT AND AFFIRMANCE

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INTEREST OF *AMICI CURIAE*[1]

Amici curiae are organizations of physicians, registered nurses and other health care professionals that share the common goal of improving health for all by ensuring access to high quality medical care for women and families that is comprehensive and evidence-based. Such medical care should include reproductive health care and services. *Amici* believe that access to the full range of FDA-approved prescription contraceptives is an essential component of effective health care for women and their families.

American College of Obstetricians and Gynecologists (ACOG) is a non-profit educational and professional organization founded in 1951. With more than 57,000 members, ACOG is the leading professional association of physicians who specialize in the health care of women. ACOG's members represent approximately 90% of all board-certified obstetricians and gynecologists practicing in the United States.

Physicians for Reproductive Health (PRH) is a doctor-led national not-for-profit organization that relies upon evidence-based medicine to promote sound reproductive health care policies. Comprised of physicians, PRH brings medical expertise to discussions of public

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1. Petitioners and Respondents have granted blanket consent to the filing of amicus briefs in this case in letters on file with the Court. Pursuant to Supreme Court Rule 37.6, *amici* state that no counsel for a party authored this brief in whole or in part and no person other than *amici*, their members, or their counsel made a monetary contribution intended to fund the preparation or submission of this brief.

policy on issues affecting reproductive health care and advocates for the provision of comprehensive reproductive health services as part of mainstream medical care.

American Academy of Family Physicians (AAFP), headquartered in Leawood, Kansas, is the national medical specialty society representing family physicians. Founded in 1947 as a not-for-profit corporation, its 120,900 members are physicians and medical students from all 50 states, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, and the Uniformed Services of the United States. The AAFP seeks to improve the health of patients, families, and communities by advocating for the health of the public and serving the needs of members with professionalism and creativity.

American Nurses Association (ANA) represents the interests of the nation's 3.1 million registered nurses. Founded over a century ago and with members in every state across the nation, ANA is comprised of state nurses associations and individual nurses. Collectively, ANA and its organizational affiliates represent more than 300,000 nurses who practice across the continuum of care and in all health care settings.

American College of Nurse-Midwives (ACNM) is the professional organization for certified nurse-midwives and certified midwives. ACNM leads the profession through education, clinical practice, research and advocacy. ACNM advocates on behalf of women and families, its members, and the midwifery profession to eliminate health disparities and increase access to evidence-based, quality care.

American College of Osteopathic Obstetricians and Gynecologists (ACOOG), which traces its origins to 1934, is passionately committed to excellence in women's health. ACOOG educates and supports osteopathic health care professionals to improve the quality of life for women.

American Medical Student Association (AMSA) is the oldest and largest independent association of physicians-in-training in the United States. Founded in 1950, AMSA is a student-governed, non-profit organization committed to representing the concerns of physicians-in-training.

American Medical Women's Association (AMWA) is a multispecialty organization comprised of physicians, residents, medical students, and health care professionals. AMWA functions at the local, national, and international level by providing and developing leadership, advocacy, education, expertise, mentoring, and strategic alliances to advance women in medicine and improve women's health.

American Society for Emergency Contraception (ASEC) is a national organization which holds as its primary mission the promotion of access to and education about emergency contraception. ASEC supports collaboration among and represents a diverse group of stakeholders in the reproductive health community whose work includes a focus on emergency contraception.

American Society for Reproductive Medicine (ASRM) is a non-profit, multidisciplinary organization with members in all 50 states and more than 100 countries worldwide. Founded in 1944, ASRM is dedicated to the advancement of the art, science, and practice of reproductive medicine.

Association of Reproductive Health Professionals (ARHP), founded in 1963, is an interdisciplinary professional association that provides evidenced-based education opportunities for frontline health care providers on a broad range of sexual and reproductive health topics.

California Medical Association (CMA) is a non-profit, incorporated professional association for physicians with approximately 41,000 members throughout the state of California. For more than 150 years, CMA has promoted the science and art of medicine, the care and well-being of patients, the protection of public health, and the betterment of the medical profession. CMA's physician members practice medicine in all specialties and settings, including providing reproductive health services.

Connecticut State Medical Society (CSMS) is a professional association consisting of approximately 6,000 physicians and medical students throughout Connecticut. These physicians provide a substantial portion of medical services to the residents of the State of Connecticut. The purposes of the association include extending medical knowledge, advancing medical science, and elevating standards of medical education. The issue of reproductive medicine is of importance to the members of CSMS, many of whom practice in this area of medical care and treatment.

International Association of Forensic Nurses (IAFN) is a non-profit membership organization comprised of forensic nurses working around the world and other professionals who support and complement the work of forensic nursing. IAFN is dedicated to the use of evidence-based forensic nursing practices and advocates

for the availability of emergency contraception to victims of sexual assault who choose to use it as a means of preventing pregnancy.

Jacobs Institute for Women's Health (JIWH) is an organization that works to improve health care for women across their lifespan and in all populations. The mission of JIWH is to identify and study issues involving the interaction of medical and social systems, facilitate informed dialogue and foster awareness among consumers and providers, and promote problem resolution, interdisciplinary coordination and information dissemination.

Maine Medical Association (MMA), founded in 1853, is a non-profit membership organization headquartered in Manchester, Maine representing the interests of over 3,800 physicians, medical students and residents in training. MMA's mission is to support Maine physicians, advance the quality of medicine in Maine and promote the health of all Maine citizens.

Massachusetts Medical Society (MMS) was founded in 1781 as a statewide professional association committed to advancing medical knowledge, developing and maintaining the highest professional and ethical standards of medical practice and health care, and promoting medical institutions. MMS is the oldest continuously operating medical society in the United States; its nearly 25,000 members include physicians practicing in all areas of medicine throughout the Commonwealth.

National Association of Nurse Practitioners in Women's Health (NPWH) is a non-profit educational

and professional organization that was established over 30 years ago and is the leading professional association of nurse practitioners who specialize in the health care of women. The mission of NPWH is to ensure the provision of quality health care to women of all ages by nurse practitioners and to protect and promote women's rights to make their own health care choices.

National Physicians Alliance (NPA) creates research and education programs that promote health and foster active engagement of physicians with their communities to achieve high quality, affordable health care for all. NPA offers a home to physicians across medical specialties who share a commitment to professional integrity and health justice.

Society for Adolescent Health and Medicine (SAHM) was founded in 1968 and is a multidisciplinary organization committed to improving the physical and psychosocial health and well-being of all adolescents through advocacy, clinical care, health promotion, health service delivery, professional development and research.

Society of Family Planning (SFP) is an academic society of researchers, clinicians and educators dedicated to improving sexual and reproductive health. Among its other activities, SFP promotes scientifically sound research by funding studies on family planning and fosters the advancement of clinical care through the development of evidence-based clinical guidelines. SFP also advances the creation of family planning knowledge to inform public policy.

Society for Maternal-Fetal Medicine (SMFM) was established in 1977 and is the membership organization for obstetricians/gynecologists who have additional formal education and training in maternal-fetal medicine. With approximately 3,000 members, the Society works to improve maternal and child health through clinical guideline development, scientific research, continuing medical education, health policy leadership, and advocacy.

Washington State Medical Association (WSMA) represents physicians and physician assistants throughout Washington state. The WSMA delivers strong advocacy that is patient focused and physician driven, working to help physicians deliver complete care patients can trust and to make Washington the best place to practice medicine and to receive care.

SUMMARY OF ARGUMENT

Recognizing the wisdom of the adage that "an ounce of prevention is worth a pound of cure,"[2] as it applies to public health, the Patient Protection and Affordable Care Act (ACA) represents a paradigm shift in health care in this country, with prevention taking a prominent role. The ACA requires non-grandfathered private health insurance plans to cover various essential preventive services with no additional cost sharing for the patient. Among the preventive services that the ACA requires be covered, without deductible or co-pay, are screenings for various conditions, such as cholesterol tests and colonoscopy screenings, pediatric and adult vaccinations, as well as women's preventive health services, including FDA-approved contraceptives prescribed by a health care provider. Well-established and evidence-based standards of medical care recommend access to contraception and contraception counseling as essential components of health care for women of childbearing age. Contraception not only helps to prevent unintended pregnancy, but it also protects the health and well-being of women and their children. The Government has a compelling interest in addressing the medical and social consequences of unintended pregnancy and promoting the widespread availability of medically appropriate contraception for all women. Contraception coverage required by the ACA through federal regulations serves these compelling interests by ensuring that all health insurance plan beneficiaries who want it have access to medically appropriate contraception without regard to their ability to pay.

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2. Attributed to Benjamin Franklin in the February 4, 1735 edition of the *Pennsylvania Gazette*.

A religious accommodation to the contraceptive coverage requirement exists, allowing certain religiously-affiliated not-for-profit employers to exclude contraceptive coverage from the health insurance they arrange for their employees by self-certifying that they qualify for the accommodation in accordance with the regulations. Federal regulations ensure that upon an employer's opt-out, the contraceptive coverage is seamlessly provided to the affected women by the group plan insurer or administrator. Because an employer's opt-out creates a coverage gap, the accommodation ensures that the gap is filled by third parties without any coverage interruption or change in services for the covered individual. The accommodation is, thus, vital to ensuring that contraceptive coverage is provided by the same insurer or administrator as the insured's other covered health services. Alternatives that require an up-front payment, require separate enrollment, or that impose administrative hurdles to obtaining contraception coverage that do not exist for other health care services are not equally effective at accomplishing the Government's compelling interests in making comprehensive preventive women's healthcare widely accessible.

The contraception coverage requirement recognizes that women of childbearing age have unique health needs and that contraception counseling and services are essential components of women's preventive health care. Decisions concerning contraceptive use, like all health care decisions, should be made by patients in consultation with their health care professionals based on the best interests of the patient. This is best accomplished when contraceptive coverage is provided within the same overall framework as a woman's other health care

services in consultation with a woman's chosen provider. The accommodation accomplishes this, while at the same time respecting an employer's sincerely held religious objections to contraception.

ARGUMENT

POINT I.

THE GOVERNMENT HAS A COMPELLING INTEREST IN FACILITATING WIDESPREAD ACCESS TO THE FULL RANGE OF FDA-APPROVED CONTRACEPTIVES

A. Contraception is an Essential Component of Women's Preventive Health Care

The ACA's coverage requirement for FDA-approved contraceptives and counseling comports with prevailing standards of care in the medical community. *See, e.g.*, Inst. of Med., *Clinical Preventive Services for Women: Closing the Gaps* 104 (2011) ("IOM Report") (noting recommendation of the use of family planning services as part of preventive care for women by numerous medical organizations, including ACOG, the American Medical Association, American Academy of Pediatrics, Society of Adolescent Medicine, and the Centers for Disease Control). In recommending that contraceptive methods and counseling be included within the preventive services required by the ACA, the Institute of Medicine recognized that the risk of unintended pregnancy affects a broad population and poses a significant impact on health. IOM Report at 8. Unintended pregnancies have long been established to have negative health consequences

for women and children and contraception services are, therefore, important public health concerns. *See, e.g.*, Jeffrey P. Mayer, *Unintended Childbearing, Maternal Beliefs, and Delay of Prenatal Care*, 24 BIRTH 247, 250-51 (1997); Suezanne T. Orr et al., *Unintended Pregnancy and Preterm Birth*, 14 PAEDIATRIC PERINATAL EPIDEMIOLOGY, 309, 312 (2000); Jennifer S. Barber et al. *Unwanted Childbearing, Health, and Mother-Child Relationships.* 40 J. HEALTH AND SOCIAL BEHAVIOR 231, 252 (1999).

Access to contraception is a medical necessity for women during approximately thirty years of their lives—from adolescence to menopause. *See* Guttmacher Inst., *Next Steps for America's Family Planning Program: Leveraging the Potential of Medicaid and Title X in an Evolving Health Care System* (2009), http://www.guttmacher.org/pubs/NextSteps.pdf; *see also* Gladys Martinez et al., *Use of Family Planning and Related Medical Services Among Women Aged 15-44 in the United States: National Survey of Family Growth, 2006-2010*, National Health Statistics Reports (Sept. 5, 2013) http://www.cdc.gov/nchs/data/nhsr/nhsr068.pdf. Without the ability to control her fertility during her childbearing years, a woman risks having approximately twelve pregnancies during her lifetime. Guttmacher Inst., *Sharing Responsibility: Women, Society and Abortion Worldwide*,18 (1999), https://www.guttmacher.org/pubs/sharing.pdf.

Virtually all American women who have had heterosexual sex have used contraception at some point during their lifetimes, irrespective of their religious affiliation. Rachel K. Jones & Joerg Dreweke, *Countering Conventional Wisdom: New Evidence on Religion and*

Contraceptive Use, Guttmacher Inst. (April 2011), http://www.guttmacher.org/pubs/Religion-and-Contraceptive-Use.pdf. At any given time, approximately two-thirds of American women of reproductive age wish to avoid or postpone pregnancy. Am. Coll. of Obstetricians & Gynecologists, GUIDELINES FOR WOMEN'S HEALTH CARE, 182 (4th ed. 2014) ("ACOG GUIDELINES"). Given women's unique reproductive health needs, access to contraception is a basic and essential preventive service for them.

1. Unintended Pregnancy and Short Interpregnancy Intervals Pose Health Risks to Women and Children

Unintended pregnancy remains a significant public health concern in the United States. Lawrence B. Finer & Mia R. Zolna, *Unintended Pregnancy in the United States: Incidence and Disparities, 2006*, 84 CONTRACEPTION 478, 478, 482 (2011). Approximately 50% of all pregnancies in the United States are unintended. Am. Coll. of Obstetricians & Gynecologists, *Increasing Use of Contraceptive Implants and Intrauterine Devices to Reduce Unintended Pregnancy*, Comm. Op. 642, 126 OBSTET. & GYNECOL. 44, 44 (2015) (citing Lawrence B. Finer & Mia R. Zolna, *Shifts in Intended and Unintended Pregnancies in the United States, 2001-2008*, 104 AM. J. PUB. HEALTH S43 (2014)). Many unintended pregnancies end in abortion. *See* Guttmacher Inst., *Unintended Pregnancy in the United States* (July 2015), http://www.guttmacher.org/pubs/FB-Unintended-Pregnancy-US.html ("In 2008, 40% of unintended pregnancies (excluding miscarriages) ended in abortion").

Women with unintended pregnancies are more likely to receive delayed prenatal care, to be anxious or depressed, and to experience domestic violence during pregnancy. Jessica D. Gipson et al., *The Effects of Unintended Pregnancy on Infant, Child, and Parental Health: A Review of the Literature*, 39 STUD. IN FAM. PLANNING 18, 22, 28-29 (2008). Women with unintended pregnancies are also less likely to breastfeed, which has been shown to have health benefits for the mother and her child. *See* Am. Acad. of Pediatrics, *Policy Statement: Breastfeeding and the Use of Human Milk*, 129 PEDIATRICS 827, 831 (2012) (noting maternal benefits of breastfeeding, including less postpartum blood loss and fewer incidents of postpartum depression and child benefits, including fewer ear infections, respiratory and gastrointestinal illnesses and fewer allergies and lower rate of obesity and diabetes).

A woman's unintended pregnancy may also have lasting effect on her child's health; low birth weight and preterm birth, which have long term sequela, are associated with unintended pregnancies. Prakesh S. Shah et al., *Intention to Become Pregnant and Low Birth Weight and Preterm Birth: A Systematic Review*, 15 MATERNAL & CHILD HEALTH J. 205, 205-206 (2011).

Contraception not only helps to avoid unwanted pregnancies, but it also helps women plan their pregnancies and determine the optimal timing and spacing of them, which improves their own health and the well-being of their children. Pregnancies that are too frequent and too closely spaced, which are more likely when contraception is more difficult to obtain, put women at significantly greater risk for permanent physical health damage. Such damage can include organ prolapse that can lead to pain, incontinence, and surgical treatments.

Additionally, women with short interpregnancy intervals are at greater risk for third trimester bleeding, premature rupture of membranes, puerperal endometritis, anemia, and maternal death. Augustin Conde-Agudelo & Jose M. Belizan, *Maternal Morbidity and Mortality Associated with Interpregnancy Interval: Cross Sectional Study*, 321 BRITISH MED. J. 1255, 1257 (2000).

Inadequate spacing between pregnancies can also be detrimental to the child. It increases the risk of low birth weight, preterm birth, and small size for gestational age. Augustin Conde-Agudelo et al., *Birthspacing and Risk of Adverse Perinatal Outcomes: a Meta -Analysis*, 295 J. AM. MED. ASS'N 1809, 1821 (2006); Bao Ping Zhu, *Effect of Interpregnancy Interval on Birth Outcomes: Findings From Three Recent U.S. Studies*, 89 INT'L J. GYNECOL. & OBSTET. S25, S26, S31 (2005); Am. Acad. Of Pediatrics & Am. Coll. of Obstetricians & Gynecologists, GUIDELINES FOR PERINATAL CARE, 202 (7th ed. 2013). Infants conceived 18 to 23 months after a previous live birth had the lowest risks of these adverse perinatal outcomes. Bao Ping Zhu et al., *Effect of the Interval Between Pregnancies on Perinatal Outcomes*, 340 NEW ENG. J. MED. 589, 590 (1999).

Because of these recognized benefits of contraceptives, the Centers for Disease Control and Prevention identified family planning as one of the greatest public health achievements of the twentieth century, finding that smaller families and longer birth intervals contribute to the better health of infants, children, and women, as well as improving the social and economic roles of women. Ctrs. for Disease Control & Prevention, *Achievements in Public Health, 1900-1999*, (Dec. 3, 1999), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4847a1.htm.

2. Women with Certain Medical Conditions or Risks Need Contraception

In addition to the positive health effects of contraception for women and their children, it also helps protect the health of those women for whom pregnancy can be hazardous, or even life-threatening. Ctrs. for Disease Control & Prevention, *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010* (June 18, 2010), http://www.cdc.gov/mmwr/pdf/rr/rr5904.pdf. Women with certain chronic conditions such as heart disease, diabetes mellitus, hypertension and renal disease, are at risk for complications during pregnancy. Other chronic conditions complicated by pregnancy include sickle-cell disease, cancer, epilepsy, lupus, rheumatoid arthritis, asthma, pneumonia and HIV. *See generally*, F. Gary Cunningham et al., WILLIAMS OBSTETRICS 958-1338 (23d ed. 2010); ACOG GUIDELINES at 187; *see also Harris v. McRae*, 448 U.S. 297, 339 (1980) (Marshall, J., dissenting) ("Numerous conditions—such as cancer, rheumatic fever, diabetes, malnutrition, phlebitis, sickle cell anemia, and heart disease—substantially increase the risks associated with pregnancy or are themselves aggravated by pregnancy."). Contraception allows women with these and other conditions to care for their own health and avoid complications for themselves or their fetuses because of an unintended pregnancy. *See* ACOG GUIDELINES at 187.

The current outbreak of the Zika virus provides an example of circumstances in which contraception may be advisable due to the risk of infectious disease and to guard against poor birth outcomes. Zika is a mosquito-

borne virus recently recognized as a global public health emergency. *See, e.g., Zika Situation Report*, World Health Organization, Feb. 5, 2016, http://www.who.int/emergencies/zika-virus/situation-report/en/. Scientists are currently researching the link between incidents of Zika infection during pregnancy and an elevated rate of babies born with microcephaly.[3] At present, there is no vaccine or anti-viral treatment for Zika. Because of the suspected impact on pregnant women and the potentially calamitous consequences for their fetuses, the CDC recommends that pregnant women postpone travel to areas where the Zika virus has been found. *See* Emily E. Petersen, et al., *Interim Guidelines for Pregnant Women During a Zika Virus Outbreak — United States*, 2016, Morbidity & Mortality Wkly Rep. (Jan. 22, 2016), http://www.cdc.gov/mmwr/volumes/65/wr/mm6502e1.htm. However, even women who do not travel to affected countries may be vulnerable to Zika infection, as there is evidence suggesting that the virus can be sexually transmitted by an infected male partner. Didier Musso et al., *Potential Sexual Transmission of Zika Virus*, 21 EMERGING INFECTIOUS DISEASES 359, 359-60 (2015), http://wwwnc.cdc.gov/eid/article/21/2/pdfs/14-1363.pdf. In response to the Zika outbreak, several countries, including Colombia, Jamaica and Honduras, have recommended that women delay pregnancy for several months and in El Salvador, the Deputy Health Minister has urged women to delay pregnancy until 2018. *See As*

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3. Microcephaly refers to a birth defect in which a baby is born with a smaller than expected head and is associated with underdevelopment of the brain. Microcephaly has been linked to various physical, developmental, and cognitive problems. *See* Ctrs. for Disease Control & Prevention, *Facts About Microcephaly*, http://www.cdc.gov/ncbddd/birthdefects/microcephaly.html.

Zika virus spreads, El Salvador asks women not to get pregnant until 2018, Washington Post (Jan, 22, 2016), https://www.washingtonpost.com/world/the_americas/as-zika-virus-spreads-el-salvador-asks-women-not-to-get-pregnant-until-2018/2016/01/22/1dc2dadc-c11f-11e5-98c8-7fab78677d51_story.html. Although the impact of the Zika virus on public health in the United States is not yet known, it is clear that access to contraception is important for women who risk exposure to the virus. Zika also makes it apparent that other, as yet unknown, public health crises could similarly impact women's need for contraception.

In addition to preventing pregnancy, contraception has other scientifically recognized health benefits for many women. Hormonal birth control helps prevent menstrual migraines, treats pelvic pain from endometriosis, and decreases the need for hysterectomy by reducing heavy menstrual bleeding. Ronald Burkman et al., *Safety Concerns and Health Benefits Associated With Oral Contraception*, 190 AM. J. OF OBSTET. & GYNECOL. S5, S12, S18 (2004). Oral contraceptives have been shown to have long-term benefits in reducing a woman's risk of developing endometrial and ovarian cancer and protecting against pelvic inflammatory disease and certain benign breast disease and short-term benefits in protecting against colorectal cancer. *Id. See also* IOM Report at 107.

B. Providing No-Cost Contraceptive Coverage Promotes Use of Effective and Appropriate Contraception

Insurance coverage has been shown to be a "major factor" for a woman when choosing a contraceptive method

and determines whether she will continue using that method. Kelly R. Culwell & Joe Feinglass, *Changes in Prescription Contraceptive Use, 1995-2002*, 110 OBSTET. & GYN. 1371, 1378 (2007). *See also* Guttmacher Inst., *Testimony of Guttmacher Institute Submitted to the Committee on Preventive Services for Women*, 8 (Jan. 12, 2011), http://www.guttmacher.org/pubs/CPSW-testimony.pdf ("Guttmacher Testimony") ("Several studies indicate that costs play a key role in the contraceptive behavior of substantial numbers of U.S. women."); Jeffrey Peipert et al. *Preventing Unintended Pregnancies by Providing No-Cost Contraception*, 120 OBSTET. & GYNECOL. 1291, 1291 (2012) (when over 9,000 study participants were offered the choice of any contraceptive method at no cost, 75% chose long-acting methods, such as the IUD or implant); Debbie Postlethwaite et al., *A Comparison of Contraceptive Procurement Pre- and Post-Benefit Change*, 76 CONTRACEPTION 360, 360 (2007) (elimination of cost-sharing for contraceptives at Kaiser Permanente Northern California resulted in significant increases in the use of the most effective forms of contraceptives); Kelly R. Culwell & Joe Feinglass, *The Association of Health Insurance with Use of Prescription Contraceptives*, 39 PERSPS. ON SEXUAL & REPROD. HEALTH 226, 226 (2007) (study reveals that uninsured women were 30% less likely to use prescription contraceptives than women with some form of health insurance).

Women regularly identify insurance coverage as having an impact on their choice of a method of contraception. Approximately one-third of women using contraception report that they would change their contraceptive method if cost were not an issue. Su-Ying Liang et al., *Women's Out-of-Pocket Expenditures and Dispensing Patterns*

for Oral Contraceptive Pills Between 1996 and 2006, 83 CONTRACEPTION 528, 531 (2011). Lack of insurance coverage deters many women from choosing a high-cost contraceptive, even if that method is best for her, and may result in her resorting to an alternative method that places her more at risk for medical complications or improper or inconsistent use, with the attendant risk of unintended pregnancy. The IUD, for example, a long-acting reversible contraceptive ("LARC") that does not require regular action by the user, is among the most effective forms of contraception, but it has up-front costs of between $500 and $1000.[4] IOM Report at 108; *see also* Megan L. Kavanaugh et al., *Perceived and Insurance-Related Barriers to the Provision of Contraceptive Services in U.S. Abortion Care Settings*, 21 WOMEN'S HEALTH ISSUES S26, S26 (3d Suppl. 2011) (finding that cost can be a barrier to the selection and use of LARCs and other effective forms of contraceptives, such as the patch, pills, and the ring). The out-of-pocket cost for a woman to initiate LARC methods was 10 times higher than a 1-month supply of generic oral contraceptives. Stacie B. Dusetzina et al., *Cost of Contraceptive Methods to Privately Insured Women in the United States*, 23 WOMEN'S HEALTH ISSUES e69, e70 (2013). Among adolescents, oral contraceptives have been found to be less effective due to faulty compliance (*e.g.*, not taking the pill every day or at the right time of day) and, therefore, LARC methods, which provide consistent protection for years after placement, are recommended, but they have forbidding up-front costs.

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4. The IUD, as well as sterilization and the implant have failure rates of 1% or less. Failure rates for injectable or oral contraceptives are 7% and 9% respectively, due to some women skipping or delaying an injection or pill. Guttmacher Testimony at 2.

Am. Acad. of Pediatrics, *Policy Statement: Contraception for Adolescents*, 134 PEDIATRICS 1244, 1246 (2014); Am. Coll. of Obstetricians & Gynecologists, *Adolescents and Long-Acting Reversible Contraception: Implants and Intrauterine Devices*, Comm. Op. 539, 120 OBSTET. & GYNECOL. 983, 983 (2012).

Women and couples are more likely to use contraception successfully when they are given their contraceptive method of choice. Jennifer J. Frost & Jacqueline E. Darroch, *Factors Associated with Contraceptive Choice and Inconsistent Method Use, United States, 2004*, 40 PERSPS. ON SEXUAL & REPROD. HEALTH 2, at 94, 103 (2008). A national survey conducted in 2004 found that one-third of women using contraception would switch methods if cost were not a factor. *Id.* A more recent study of over 9,000 adolescents and women desiring reversible contraception, for which all participants received their choice of contraceptive at no cost, resulted in a significant reduction in abortion rates and teenage birth rates. The study concluded that "unintended pregnancies may be reduced by providing no-cost contraception and promoting the most effective contraceptive methods." Peipert et al., 120 OBSTET. & GYNECOL. at 1291.

Even seemingly insubstantial additional cost requirements can dramatically reduce women's use of health care services. Adam Sonfield, *The Case for Insurance Coverage of Contraceptive Services and Supplies Without Cost-Sharing*, 14 GUTTMACHER POL'Y REV. 7, 10 (2011). Pre-ACA conventional coverage alone has been shown to be insufficient, as co-pays and deductibles required by insurance plans may still render the most effective contraception unaffordable. *See* Am. Coll. of Obstetricians

& Gynecologists, *Access to Emergency Contraception*, Comm. Op. 542, 120 OBSTET. & GYNECOL. 1250, 1251 (2012) (citing Jodi Nearns, *Health Insurance Coverage and Prescription Contraceptive Use Among Young Women at Risk for Unintended Pregnancy*, 79 CONTRACEPTION 105 (2009)) (financial barriers, including lack of insurance, or substantial co-payments or deductibles, may deprive women of access to contraception).

The data compiled over several decades demonstrates the significant health benefits to women and children when women are able to prevent getting pregnant. The government has a compelling interest in reducing unintended pregnancies by facilitating access to the full range of FDA-approved contraceptives so that women who choose to use contraception can make their decisions based on medical suitability rather than ability to pay.

POINT II.

THE ACCOMMODATION IS THE LEAST RESTRICTIVE MEANS OF EFFECTIVELY PROVIDING CONTRACEPTIVE COVERAGE TO PLAN BENEFICIARIES

A. The Proposed Alternatives Are Not As Effective At Accomplishing the Government's Compelling Objectives

The Religious Freedom Restoration Act of 1993 ("RFRA") permits a regulation that furthers compelling government interests to substantially burden a person's religious exercise if it is "the least restrictive means of furthering that compelling government interest." 42

U.S.C. § 2000bb-1(b).[5] As framed by each of the separate opinions in *Hobby Lobby*, this prong of the RFRA analysis addresses whether proposed alternatives are as effective as the challenged regulation at accomplishing the Government's objectives. *See Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2759 (2014) (there are "other

5. As health professionals, *amici* do not address the first prong of the RFRA analysis, whether the accommodation substantially burdens Petitioners' sincere religious objections to providing or facilitating the insurance coverage of some or all contraceptive methods. *See* 42 U.S.C. § 2000bb-1. However, while acknowledging Petitioners' differing theological beliefs as to whether some or all forms of contraception are sinful, *amici* note that there is no scientific evidence for the erroneous belief that any of the FDA-approved forms of contraception are abortifacients, as that term is understood scientifically. The medical and scientific communities have long defined pregnancy as beginning upon implantation. *See, e.g.*, OBSTETRIC-GYNECOLOGIC TERMINOLOGY: WITH SECTION ON NEONATOLOGY AND GLOSSARY OF CONGENITAL ABNORMALITIES 299, 327 (E.G. Hughes, ed., F.A. Davis Co. 1972). An "abortifacient," therefore, refers only to drugs or devices that work after implantation to end a pregnancy, not those that prevent it. As many of these same *amici* noted in briefing in the *Hobby Lobby* case, none of the FDA-approved emergency contraceptives or IUDs are abortifacients; rather, they prevent unintended pregnancy from occurring and thereby prevent situations in which a woman might otherwise consider abortion. *See* Brief of Amici Curiae Physicians for Reproductive Health et al. in Support of the Government's Petition for a Writ of Certiorari in *Burwell* v. *Hobby Lobby Stores, Inc.*, No. 13-354. Studies since the briefing in *Hobby Lobby* reinforce this conclusion, including a 2015 study on the effects of ella's UPA on embryo attachment, which "demonstrates for the first time that UPA in the dose used for [emergency contraception] does not affect human embryo or implantation process . . ."). Cecilia Berger et al., *Effects Of Ulipristal Acetate On Human Embryo Attachment And Endometrial Cell Gene Expression In An In Vitro Co-Culture System*, 30 HUMAN REPRODUCTION 4, 6 (2015).

ways in which Congress or HHS could *equally ensure* that every woman has cost-free access . . .) (plurality opinion) (emphasis added); *id* ("HHS has already devised and implemented a system that . . . ensur[es] that the employees of these entities have *precisely the same access* to all FDA-approved contraceptives as employees of companies whose owners have no religious objections . . .") (emphasis added); *id.* at 2782 (the accommodation "serves HHS's stated interests *equally well*") (emphasis added); *id.* (no reason why "this accommodation would fail to protect the asserted needs of women *as effectively* as the contraceptive mandate . . .:) (emphasis added); *id.* at 2786 (the "accommodation *equally* furthers the Government's interest . . .") (Kennedy, concurring) (emphasis added); *id.* at 2801-02 (finding "no less restrictive, *equally effective* means . . .")(Ginsburg, dissenting, with Sotomayor, Breyer, and Kagan joining) (emphasis added). *See also Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 429 (2006) (challenged regulation stands if "proposed less restrictive alternatives are less effective . . ") (citing *Ashcroft v. Am. Civil Liberties Union*, 542 U. S. 656, 666 (2004) (considering efficacy of alternatives and finding that proposed less restrictive means were not shown to be "less effective than the [challenged] restrictions . . ."); *Reno v. Am. Civil Liberties Union*, 521 U.S. 844, 874 (1997) (challenged regulation does not survive strict scrutiny "if less restrictive alternatives would be *at least as effective* in achieving the legitimate purpose that the statute was enacted to serve.") (emphasis added); *F.C.C. v. League of Women Voters of California*, 468 U.S. 364, 395 (1984) (observing that the Government's interest can be "*fully satisfied* by less restrictive means that are readily available") (emphasis added).

None of the alternatives to the accommodation that have been proposed here is as effective as the contraception coverage requirement at promoting widespread access to effective and medically appropriate contraception.

B. The Accommodation is the Least Restrictive Means of Providing Seamless Access to Contraceptives

1. The Provider-Patient Relationship is Particularly Important on Matters of Reproductive Health, Including Contraception

The provider-patient relationship is essential to all health care. The health care professional and the patient share responsibility for the patient's health, and the well-being of the patient depends upon their collaborative efforts. Am. Med. Ass'n, *Opinion 10.01- Fundamental Elements of the Patient-Physician Relationship*, http://www.ama-assn.org//ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion1001.page. *See also* Am. Coll. of Obstetricians & Gynecologists, *Elective Surgery and Patient Choice*, Comm. Op. 578, 122 OBSTET. & GYNECOL. 1134, 1135 (2013) ("The goal should be decisions reached in partnership between patient and physician."). More than 50% of women with a regular health care provider report long-term relationships of more than five years with their providers. Kaiser Fam. Found., *Women and Health Care: A National Profile*, 34 (July 2005), https://kaiserfamilyfoundation.files.wordpress.com/2013/01/women-and-health-care-a-national-profile-key-findings-from-the-kaiser-women-s-health-survey.pdf.

Within the provider-patient relationship, the provider's respect for the patient's autonomy is fundamental. Am. Coll.

of Obstetricians & Gynecologists, *Code of Professional Ethics*, http://www.acog.org/About_ACOG/~/media/Departments/National%20Officer%20Nominations%20Process/ACOGcode.pdf. "In medical practice, the principle of respect for autonomy implies personal rule of the self that is free . . . from controlling interferences by others." Am. Coll. of Obstetricians & Gynecologists, *Ethical Decision Making in Obstetrics and Gynecology*, Comm. Op. 390, 110 OBSTET. & GYNECOL. 1479, 1481 (2007). *Cf. Doe v. Bolton*, 410 U.S. 179, 197 (1973) (recognizing a "woman's right to receive medical care in accordance with her licensed physician's best judgment . . ."); *Cruzan by Cruzan v. Dir., Missouri Dep't of Health*, 497 U.S. 261, 289 (1990) (O'Connor, J., concurring) (recognizing "patient's liberty, dignity, and freedom to determine the course of her own treatment").

Deciding on the best form of contraception for any specific patient should take place within this established provider-patient relationship. This is particularly true given the highly personal nature of the reproductive health and family planning services that are at issue here. Based on a recent evidence-based report issued by the CDC, ACOG stresses the importance of "effective and efficient patient-practitioner communication about reproductive life planning . . .."). Am. Coll. of Obstetricians & Gynecologists, *Reproductive Life Planning to Reduce Unintended Pregnancy*, Comm. Op. 654, 127 OBSTET. & GYNECOL. 66, 67 (Feb. 2016). Prescribing birth control is typically far more intimate and intrusive than signing a prescription pad; in addition to medical screening to ensure that a particular birth control method is not contraindicated, a pelvic exam is required when prescribing a diaphragm or cervical cap or inserting an IUD. A pelvic exam may also be warranted

before prescribing other types of contraceptives, based on the woman's medical history. Am. Coll. of Obstetricians & Gynecologists, *Well-Woman Visit*, Committee Op. 534, 120 OBSTET. & GYNECOL. 421, 422 (2012). Women should be able to make these personal decisions – decisions that often require sharing intimate details of their sexual history and family planning – with providers they have sought out and trust.

For many women of reproductive age, their well-woman visits are their primary, if not exclusive contact with the health care system. ACOG GUIDELINES at 201. Yet, the proposed alternatives to the accommodation identified by Petitioners would remove contraceptive care from a woman's routine health services and require her to use a two-tiered system of access and coverage, one for her overall health needs and one limited to contraceptive care. *See, e,g.,* Petitioners Br. in 14-1418 at 75-82 (proposing that women obtain separate insurance on the health care exchanges to obtain contraceptive coverage; or receive contraceptive coverage from a separate Title X clinic; or pay out of pocket in the hopes of recovering a tax credit in the future); Petitioners Br. in 15-35, 15-105, 15-119, and 15-191 at 72, 75-76 (suggesting that women desirous of contraceptive coverage could forego their employer-sponsored plan and enroll in a plan offered on the health care exchange, or obtain contraceptives through a Title X clinic). No alternative proposed by Petitioners or their amici does what the accommodation does: provide plan beneficiaries with cost-free contraceptives from their pre-existing health insurer. In its interim order in *Wheaton College*, this Court recognized that it was permissible that plan beneficiaries receive contraception coverage from their existing insurer or administrator; effectuating

coverage in that manner did not render the regulation impermissible. *Wheaton Coll. v. Burwell*, 134 S. Ct. 2806, 2807 (2014) ("[n]othing in this order precludes the Government from relying on this notice, to the extent it considers it necessary, to facilitate the provision of full contraceptive coverage under the Act.").

Unlike the result in *Wheaton College*, the alternatives proposed by Petitioner all entail "logistical and administrative obstacles" to obtaining contraceptives that are avoided through the accommodation. 78 Fed.Reg. 39888. For this reason, none is as effective as the existing accommodation, which stands as the least restrictive means of furthering the Government's objectives.

2. De-Linking Contraceptive Services from Routine Health Care Will Likely Reduce Contraception Utilization

The alternatives to the accommodation that Petitioners propose all create some additional cost or administrative hurdle to contraceptive coverage that is absent from the challenged accommodation and that compromise the Government's objective of facilitating access to contraception for women who want it. In varying degrees, all require that contraceptive coverage be provided outside of a woman's regular health services, whether it is through insurance coverage obtained separately, or obtaining services only at designated facilities, or requiring a cash outlay only possibly reimbursed through a tax credit. As such, none of the alternatives results in the seamless coverage effectuated by the accommodation and for this reason alone, they fail to provide "precisely the same access to all FDA-approved contraceptives as employees

of companies whose owners have no religious objections to providing such coverage." *Hobby Lobby*, 134 S.Ct. at 2759.

Petitioners' tax credit proposal would only defray the cost of contraception for those women eligible for a tax credit and would, in any event, impose an up-front cost for contraception that not only undermines the Government's objective of providing contraception without cost-sharing, but also serves as a barrier to contraceptive use, especially for women of modest means. *See* Point I.B, *supra*. Similarly, requiring women who want coverage for contraceptive services to forego their employer-sponsored plans and obtain individual insurance would likely result in higher insurance costs to them because, *inter alia*, their employers would not be contributing to the cost of premiums. These added costs, which would be directly attributable to a woman seeking coverage for contraceptive services, are precisely what the ACA intended to prevent. See 42 U.S.C. § 300gg-13(a)(4) (requiring coverage of preventive health services without any cost sharing requirements).

Petitioners' remaining proposals would impose other obstacles to satisfying the Government's objective of making contraception more accessible. Petitioners suggest that the Government could create a new health plan on the exchange that would cover contraceptive services or could expand the Title X program to allow plan beneficiaries of objecting employers to obtain contraceptive services at Title X clinics. These proposals detach contraceptive services from a woman's routine health care and require that she obtain contraceptives through a separate insurance network - one that may have different eligibility criteria and/or different in-network providers - or at a clinic. These proposals increase the risk that she will not

make use of this stand-alone contraception coverage and cease using contraception regularly, risking an unintended pregnancy.

Each of these proposed alternatives requires a woman to take additional steps for contraceptive coverage beyond what is required for other covered services - by enrolling in a separate plan on an exchange, making a separate visit for contraceptive services, and/or or paying out of pocket for covered services and seeking a tax credit. Just as direct cost barriers deter women from using appropriate contraception, or from using appropriate contraception consistently, administrative or logistical barriers are also likely to result in lower or less consistent utilization rates. "Considerable research shows that modest procedural requirements—completing a simple form or even checking a box—can greatly lower participation levels in public and private benefit programs." Frederic Blavin, et al., *Using Behavioral Economics to Inform the Integration of Human Services and Health Programs under the Affordable Care Act* at ii (July 2014); *see also* Dahlia K. Remler & Sherry A. Glied, *What Other Programs Can Teach Us: Increasing Participation in Health Insurance Programs*, 93 AMERICAN J. PUB. HEALTH 67, 67 (2003) (recognizing impact of nonfinancial features, such as administrative complexity, on enrollment); Cass R. Sunstein, *Nudges.gov: Behavioral Economics and Regulation* 3 (Feb. 2013), http://tinyurl.com/nudgesgov (reducing paperwork burdens results in greater participation in public programs).

The most effective means of ensuring high utilization rates is for benefits to be provided automatically. Remler & Glied, *supra* (observing, as a "striking pattern," that

programs where "no 'extra action' is required," have the highest "take up" or participation rates). In the context of retirement savings, for example, 401(k) enrollment is significantly higher in companies where employees must opt out of the program as compared to companies where employees must enroll to participate. *See* John Beshears et al., *The Importance of Default Options for Retirement Savings Outcomes: Evidence from the United States*, SOCIAL SECURITY POLICY IN A CHANGING ENVIRONMENT, at 171 (2009). In Louisiana, when a child's enrollment in Medicaid was de-linked from the Supplemental Nutrition Assistance Program (SNAP) in 2011, thus requiring parents to check a box on the SNAP application form, enrollment in Medicaid through SNAP dropped off by an average of 62 percent per month. Blavin, *supra* at 8 (noting that de-linking programs caused decline notwithstanding that "the check-box was highlighted, bolded, prominently placed" and written in clear language).[6] Similarly, even the seemingly minor burden of having to renew or refill prescriptions more frequently results in reduced compliance. *See* Diana Greene Foster et al., *Number of Oral Contraceptive Pill Packages Dispensed and Subsequent Unintended Pregnancies*, 117 OBSTET. & GYNECOL. 566, 570-71 (2011) ("Dispensing a 1-year supply [of oral contraceptives] is associated with a significant reduction in the odds of conceiving an unplanned pregnancy compared with dispensing just one or three packs.").

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6. Numerous other studies demonstrate the impact of requiring prospective participants to affirmatively opt-in on participation rates, including with respect to organ donation, car insurance preferences, and online privacy settings and information sharing. *See* Cass R. Sunstein, *Deciding by Default*, 162 U. Pa. L. Rev. 1 (2013) (summarizing studies).

Under the accommodation, prescription contraceptives are covered seamlessly and automatically as part of a woman's health insurance package. If access to appropriate, cost-free contraception is removed from women's routine health care services or is made more difficult to obtain, the likely result is that many women will simply not use contraception or will use an imperfect form of contraception inconsistently or improperly, with a concomitant increase in unintended pregnancies with all their consequences. Imposing these added layers of coverage eligibility make all of these alternatives a poor substitute for the accommodation at promoting access to cost-free contraceptive services.

Exacerbating the administrative barriers to obtaining contraceptive coverage is that all of the proposed alternatives leave women at risk of informational gaps as to how to obtain coverage for contraceptives outside of their employer-provided plan. All of the alternatives would require that plan beneficiaries be notified that they are entitled to receive coverage for contraceptives elsewhere and be given clear, timely and easily followed information as to how to obtain it. Yet the same employers that object to informing the government or their health plan administrators that they opt out of the coverage requirement, are also likely to object to providing necessary information about obtaining coverage to plan beneficiaries. Any failure to adequately inform plan beneficiaries how no-cost contraceptive coverage can be obtained (or even that it is available at all) necessarily impedes the government's objective of promoting contraceptive coverage and deprives plan beneficiaries of the rights secured by the ACA coverage requirement.

Additionally, even if a woman is inclined to obtain contraceptive coverage outside of her regular health system, as proposed by Petitioners, she may not be able to choose her provider, or see the same practitioner for follow-up visits. In either case, the quality of care she receives may be severely compromised as a result. Continuity of care has been shown to affect continuity and consistency of contraceptive use and women who are not satisfied with their health care provider, who do not see the same provider at visits, or who feel they cannot call their provider between visits are more likely to use contraception inconsistently. *See* Frost & Darroch, 40 PERSPS. ON SEXUAL & REPROD. HEALTH at 100.

Contraceptive services ought to be provided by the health care practitioner that the woman has selected for her health care needs and with whom she has a professional relationship and is comfortable discussing private medical information. These services should be available as part of a woman's routine health services and should not depend on her overcoming additional hurdles that are not required for other preventive services. This best ensures a woman's access to and use of the contraceptive method that is medically appropriate and best suited to her individual circumstances. The accommodation does this and is the most effective means of furthering the Government's compelling interest in making important preventive health services more widely attainable.

CONCLUSION

For the foregoing reasons, as well as those in the Government's Brief, the judgments of the Courts of Appeals should be *affirmed*.

Dated: February 17, 2016

Respectfully submitted,

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